

Propper Hi-Dri® Dry Heat Indicator: Conformance with ISO 11140-1:2014

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The Propper Hi-Dri® Dry Heat strip is a Type 4 chemical indicator that can be used in all dry heat sterilizers operating at 180°C. When used as directed, the indicators give visible proof of adequate exposure to 180°C for 60 minutes. The indicator initial color is light-blue, and after exposure to dry heat it changes to brown.

Performance requirements:

ISO 11140-1:2014 Sterilization of Healthcare products – Chemical Indicators – Part 1: general requirements specifies, that Dry Heat® indicator should demonstrate full end-point color change at specified by manufacturer exposure (“Pass” result). The indicator should not reach end-point (show “fail” result) at - 25% time and -5°C exposure. For Hi-Dri® indicator those test point would be:

Requirement	Time	Temperature
Pass point	60 min	180°C
Fail point	45 min	175°C

A series of tests were conducted by Propper Mfg. Co., Inc. to determine effective performance of Hi-Dri® indicator inside Propper’s Dry Heat Resistometer. Randomly chosen samples from three lots of products have been tested. For each point of testing 10 indicators from each lot were used. The testing was performed in July-August 2012. At that point ISO 11140-1:2005 was in effect, the requirements for Dry Heat indicators were the same. The detailed description of the performance testing and retained samples are on file at Propper and described in internal Professional Information Report, Dry Heat Indicator: ISO 11140-1 compliance Testing. The study was performed by Director of R&D Michael Tambasco.

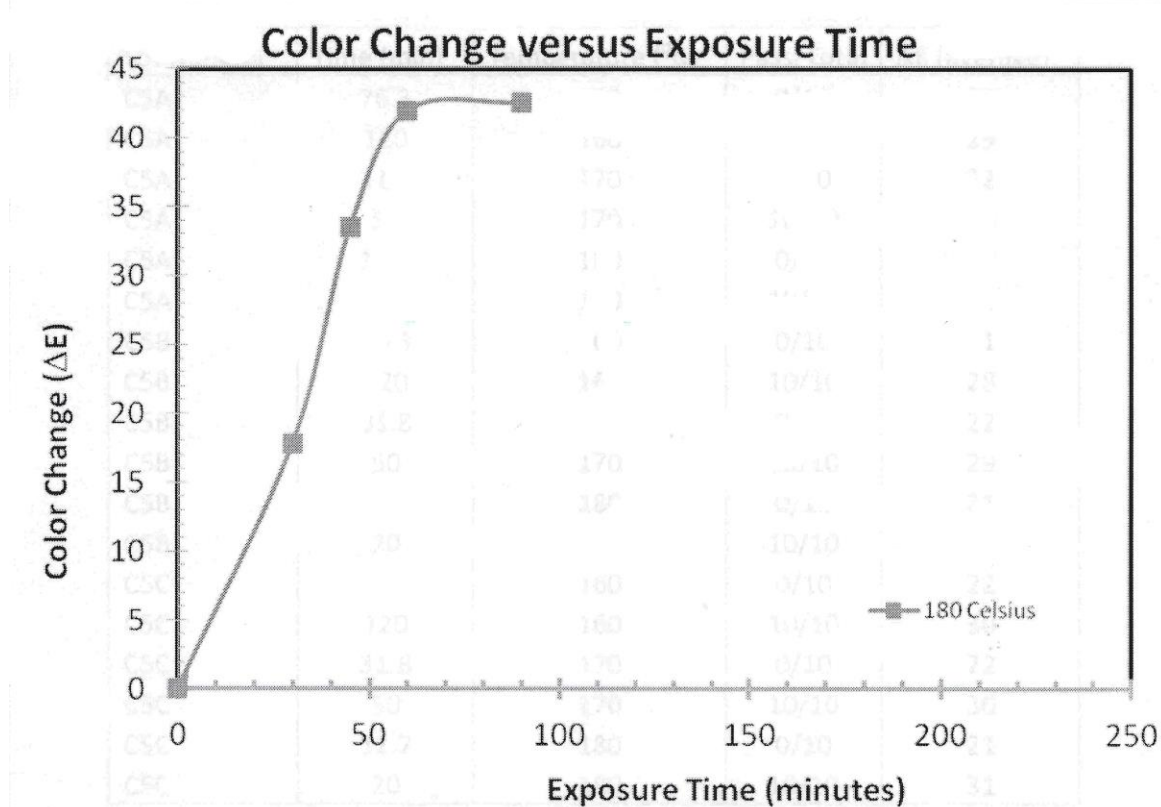
The results of Hi-Dry® indicator testing were evaluated visually and using spectrophotometer ColorEye XTN.

1. Visual evaluation of the test results: all indicators in “Pass” cycles achieved brown color. All indicators in “Fail” cycles did not reach end-point color and remained Crème or yellow color, some with very light brown inclusions.
2. Spectrophotometer results: for the spectrophotometric measurements, the colors are described using CIE L*a*b* system, where L* represents the lightness of a color (on a scale from 0 for black to 100 for white), a* represents the position between green (negative values) and red (positive), and b* represents the position between blue (negative) and yellow (positive). The quantity ΔE represents the absolute difference between two sets of color measurements. Two color which yield a ΔE that is less than 1 appear identical to the human eye. The spectrophotometer readings are used because

they serve as an objective measurement independent on difference in human eyes and observation conditions. Also, the spectrophotometer measurements can be documented.

Lot #	Time, min	Temperature °C	Pass/Total	ΔE average
180A	60	180	10/10	42
180A	45	175	0/10	33
180B	60	180	10/10	40
180B	45	175	0/10	30
180C	60	180	10/10	44
180C	45	175	0/10	35

The test results show that Hi-Dry[®] indicator is compliant with the requirements described in ISO 11140-1:2014. The indicator begins as a very light blue, and undergoes a transition to dark brown when successfully exposed to 180°C dry heat cycle for 60 min. Insufficient exposure will result in a lighter brown, yellow or orange color of the entire or part of the indicator spot which is interpreted as a “fail” result.



Conclusion: Proper Hi-Dry[®] dry heat sterilization indicator conforms to the requirements of ISO 11140-1:2014 as Type 4 indicator.

Additional product information:

1. Reorder number: 26101800
2. Visual representation: unprocessed indicator strip - ink color is light blue.
3. Storage: RH 35-65%, Temperature: +15°C +32°C, Protect from light.

